

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Helipur H plus N

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture

Instrument disinfectant

Disinfection and cleaning of surgical instruments, flexible and rigid endo scopes, laboratory and anaesthesia equipment

1.3. Details of the supplier of the safety data sheet

Manufacturer

Company name: B. Braun Medical AG
Street: Seesatz 17
Place: CH-6204 Sempach
Responsible Department: Zentrale
Telephone: +41 (0) 58 / 258 50 00
E-Mail: info.bbmch@bbraun.com
Responsible for the safety data sheet: sds@gbk-ingelheim.de

Supplier

Company name: B. Braun Melsungen AG
Street: Carl-Braun-Straße 1
Place: D-34212 Melsungen
Responsible Department: Zentrale Service-Bereiche / Logistik und Supply Chain
Telephone: +49 (0) 5661 / 71-4422
E-Mail: logistics.service@bbraun.com

1.4. Emergency telephone number: INTERNATIONAL: +49 - (0) 6132 - 84463, GBK GmbH (24h - 7d/w - 365d/a)
In England and Wales: NHS 111 In Scotland: NHS 24 - dial 111

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture according to 1272/2008/EC

Hazard categories:

Acute toxicity: Acute Tox. 4

Acute toxicity: Acute Tox. 4

Skin corrosion/irritation: Skin Corr. 1B

Serious eye damage/eye irritation: Eye Dam. 1

Respiratory or skin sensitisation: Resp. Sens. 1

Respiratory or skin sensitisation: Skin Sens. 1

Specific target organ toxicity - single exposure: STOT SE 3

Hazardous to the aquatic environment: Aquatic Chronic 3

Hazard Statements:

Harmful if swallowed or if inhaled.

Causes severe skin burns and eye damage.

May cause an allergic skin reaction.

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May cause respiratory irritation.

Harmful to aquatic life with long lasting effects.

2.2. Label elements

Hazard components for labelling

Glycolic acid ethoxylate octyl ether

Glutaraldehyde

Fatty alcohol polyglycol ether

(R)-p-Mentha-1,8-diene

Signal word: Danger

Pictograms:



Hazard statements

- H302+H332 Harmful if swallowed or if inhaled.
- H314 Causes severe skin burns and eye damage.
- H317 May cause an allergic skin reaction.
- H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- H335 May cause respiratory irritation.
- H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

- P260 Do not breathe vapour.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
- P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P310 Immediately call a POISON CENTER/doctor.

Special labelling of certain mixtures

- EUH071 Corrosive to the respiratory tract.

Additional advice on labelling

In accordance with section 1.5.2 of Annex I of the European Regulation (EC) No 1272/2008, following H and P statements may be omitted for containers < 125 ml: H302+H332, H335

2.3. Other hazards

According to Regulation (EC) No 1907/2006 (REACH) none of the substances, contained in this product are a PBT / vPvB substance.

Vapours may form explosive mixture with air.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Acidic concentrate with glutaraldehyde and isopropanol

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
53563-70-5	Glycolic acid ethoxylate octyl ether			< 15 %
	Skin Irrit. 2, Eye Dam. 1; H315 H318			
111-30-8	Glutaraldehyde			12 %
	203-856-5	605-022-00-X	01-2119455549-26	
	Acute Tox. 2, Acute Tox. 3, Skin Corr. 1B, Resp. Sens. 1, Skin Sens. 1A, STOT SE 3, Aquatic Acute 1, Aquatic Chronic 2; H330 H301 H314 H334 H317 H335 H400 H411 EUH071			
127036-24-2	Fatty alcohol polyglycol ether			< 10 %
	Acute Tox. 4, Eye Dam. 1; H302 H318			
67-63-0	Propan-2-ol			7,5 %
	200-661-7	603-117-00-0	01-2119457558-25	
	Flam. Liq. 2, Eye Irrit. 2, STOT SE 3; H225 H319 H336			
5989-27-5	(R)-p-Mentha-1,8-diene			< 0,25 %
	227-813-5	601-029-00-7	01-2119529223-47	
	Flam. Liq. 3, Skin Irrit. 2, Skin Sens. 1, Asp. Tox. 1, Aquatic Acute 1, Aquatic Chronic 1; H226 H315 H317 H304 H400 H410			

Full text of H and EUH statements: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

Remove contaminated soaked clothing immediately.
If you feel unwell, seek medical advice.

After inhalation

Consult a physician after significant exposure.
Move to fresh air in case of accidental inhalation of vapours or decomposition products.

After contact with skin

Wash off immediately with soap and plenty of water.
Treat subsequently with skin cream.
Consult a physician.

After contact with eyes

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
Summon a doctor immediately.

After ingestion

Induce vomiting only upon the advice of a physician.
Drink plenty of water.
Summon a doctor immediately.

4.2. Most important symptoms and effects, both acute and delayed

Harmful if swallowed or if inhaled.
May cause an allergic skin reaction.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause respiratory irritation.
Causes severe skin burns and eye damage.
Corrosive to the respiratory tract.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptoms.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Product is ignitable, but does not keep burning.

Fire-extinguishing activities according to surrounding.

Unsuitable extinguishing media

Full water jet.

5.2. Special hazards arising from the substance or mixture

Fire may produce:

carbon monoxide and carbon dioxide

Irritant/corrosive, flammable as well as toxic distillation gases (carbonization gases).

5.3. Advice for firefighters

Use breathing apparatus with independent air supply.

Protective suit.

Additional information

Cool containers at risk with water spray jet.

Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

In case of vapour formation use respirator.

Avoid contact with skin, eyes and clothing.

Ensure adequate ventilation.

Use personal protective clothing.

6.2. Environmental precautions

Do not discharge into the drains/surface waters/ground water.

6.3. Methods and material for containment and cleaning up

Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder).

Shovel into suitable container for disposal.

6.4. Reference to other sections

Observe protective instructions (see Sections 7 and 8).

Information for disposal see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Keep container tightly closed.

Keep a good ventilation and air-exhaust at the place of work.

Do not breathe vapours.

Avoid contact with skin, eyes and clothing.

Advice on protection against fire and explosion

Product is ignitable, but does not keep burning.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep containers tightly closed in a dry, well-ventilated place.

Hints on joint storage

Incompatible with strong acids and oxidizing agents.

Further information on storage conditions

Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

Instrument disinfectant

Disinfection and cleaning of surgical instruments, flexible and rigid endo scopes, laboratory and anaesthesia equipment

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m ³	fibres/ml	Category	Origin
111-30-8	Glutaraldehyde	0.05	0.2		TWA (8 h)	WEL
		0.05	0.2		STEL (15 min)	WEL
67-63-0	Propan-2-ol	400	999		TWA (8 h)	WEL
		500	1250		STEL (15 min)	WEL

8.2. Exposure controls

Appropriate engineering controls

Ensure adequate ventilation, especially in confined areas.

Protective and hygiene measures

Wash hands before breaks and immediately after handling the product.

When using do not eat or drink.

Take off immediately all contaminated clothing.

Avoid contact with eyes, skin or mucous membrane.

Eye/face protection

Safety goggles with side protection (EN 166).

Eye wash bottle with pure water (EN 15154).

Hand protection

Also suitable are gloves made of:

Polychloropren - CR (0,5 mm): Breakthrough time > 2 h

Nitrile rubber/nitrile latex - NBR (0,35 mm): Breakthrough time > 8 h

Butyl rubber - Butyl (0,5 mm): Breakthrough time > 8 h

Fluoro-rubber - FKM (0.4 mm): Breakthrough time > 8 h

This recommendation refers exclusively to the chemical compatibility and the lab test conforming to EN 374 carried out under lab conditions.

Requirements can vary as a function of the use. Therefore it is necessary to adhere additionally to the recommendations given by the manufacturer of protective gloves.

Skin protection

Long sleeved clothing (DIN EN ISO 6530)

Apron (EN 467).

Respiratory protection

In case of insufficient ventilation wear suitable respiratory equipment (gas filter type A) (EN 14387).

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	Green
Odour:	Aldehyde-like, Perfumed (scented)

pH-Value (at 20 °C): approx. 4,5 Concentrate

Changes in the physical state

Initial boiling point and boiling range: approx. 82 °C

Flash point: 37 - 42 °C DIN 51755 *)

Lower explosion limits: 2 vol. %

Upper explosion limits: n.d.

Ignition temperature: 425 °C

Density (at 20 °C): approx. 1,02 g/cm³

Water solubility: Miscible
(at 20 °C)

Solvent content: < 10 %

9.2. Other information

*) Product is ignitable, but does not keep burning.

SECTION 10: Stability and reactivity

10.1. Reactivity

No decomposition if stored and applied as directed.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Reactions with acids and strong oxidizing agents.

10.4. Conditions to avoid

To avoid thermal decomposition, do not overheat.

10.5. Incompatible materials

Strong acids and oxidizing agents

10.6. Hazardous decomposition products

Irritant/corrosive, flammable as well as toxic distillation gases (carbonization gases).
Carbon monoxide and carbon dioxide

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

Harmful if swallowed or if inhaled.

No toxicological data available.

Irritation and corrosivity

Causes severe skin burns and eye damage.

Sensitising effects

May cause an allergic skin reaction. (Glutaraldehyde; (R)-p-Mentha-1,8-diene)

May cause allergy or asthma symptoms or breathing difficulties if inhaled. (Glutaraldehyde)

STOT-single exposure

May cause respiratory irritation. (Glutaraldehyde)

Severe effects after repeated or prolonged exposure

Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Additional information on tests

Classification in compliance with the assessment procedure specified in the Regulation (EC) no 1272/2008.

SECTION 12: Ecological information

12.1. Toxicity

Ecological data are not available.

Harmful to aquatic life with long lasting effects.

12.2. Persistence and degradability

The surfactant(s) contained in this preparation complies(comply) with the biodegradability criteria as laid down in Regulation (EC) No.648/2004 on detergents. Data to support this assertion are held at the disposal of the competent authorities of the Member States and will be made available to them, at their direct request or at the request of a detergent manufacturer.

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

According to Regulation (EC) No 1907/2006 (REACH) none of the substances, contained in this product are a PBT / vPvB substance.

12.6. Other adverse effects

Hazardous water pollutant.

Further information

Ecological injuries are not known or expected under normal use.
Product is not allowed to be discharged into aquatic environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

Where possible recycling is preferred to disposal.
Can be incinerated, when in compliance with local regulations.

Waste disposal number of waste from residues/unused products

070604 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of fats, grease, soaps, detergents, disinfectants and cosmetics; other organic solvents, washing liquids and mother liquors; hazardous waste

Contaminated packaging

Empty containers should be taken for local recycling, recovery or waste disposal.
Contaminated packaging should be emptied as far as possible and after appropriate cleansing may be taken for reuse.
Packaging that cannot be cleaned should be disposed of like the product.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number: UN 1903
14.2. UN proper shipping name: DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Glutaraldehyde)
14.3. Transport hazard class(es): 8
14.4. Packing group: II
Hazard label: 8



Classification code: C9
Limited quantity: 1 L / 30 kg
Excepted quantity: E2
Transport category: 2
Hazard No: 80
Tunnel restriction code: E

Inland waterways transport (ADN)

14.1. UN number: UN 1903
14.2. UN proper shipping name: DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Glutaraldehyde)
14.3. Transport hazard class(es): 8
14.4. Packing group: II
Hazard label: 8



Classification code: C9

Helipur H plus N

Revision date: 08.08.2018

Revision No: 1,4

Product code: 00056-0161

Limited quantity: 1 L / 30 kg
Excepted quantity: E2

Marine transport (IMDG)

14.1. UN number: UN 1903
14.2. UN proper shipping name: DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Glutaraldehyde)
14.3. Transport hazard class(es): 8
14.4. Packing group: II
Hazard label: 8



Marine pollutant: No
Limited quantity: 1 L / 30 kg
Excepted quantity: E2
EmS: F-A, S-B

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number: UN 1903
14.2. UN proper shipping name: DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Glutaraldehyde, Solution)
14.3. Transport hazard class(es): 8
14.4. Packing group: II
Hazard label: 8



Limited quantity Passenger: 0.5 L
Passenger LQ: Y840
Excepted quantity: E2
IATA-packing instructions - Passenger: 851
IATA-max. quantity - Passenger: 1 L
IATA-packing instructions - Cargo: 855
IATA-max. quantity - Cargo: 30 L

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: no

14.6. Special precautions for user

Handle in accordance with good industrial hygiene and safety practice.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

The transport takes place only in approved and appropriate packaging.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)
2004/42/EC (VOC): < 10 %

Additional information

Regulation (EC) No 648/2004 (Regulation on detergents):
Anionic surfactants 5 - 15 %, Non-ionic surfactants < 5 %, Parfum < 5 %
Ingredients subject to the labelling obligation according to SCCP:
Limonene

National regulatory information

Employment restrictions:

Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

15.2. Chemical safety assessment

For this substance a chemical safety assessment has not been carried out.

SECTION 16: Other information

Abbreviations and acronyms

ADR = Accord européen relatif au transport international des marchandises Dangereuses par Route

RID = Règlement concernant le transport international ferroviaire de marchandises dangereuses

ADN = Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure

IMDG = International Maritime Code for Dangerous Goods

IATA/ICAO = International Air Transport Association / International Civil Aviation Organization

MARPOL = International Convention for the Prevention of Pollution from Ships

IBC-Code = International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

REACH = Registration, Evaluation, Authorization and Restriction of Chemicals

CAS = Chemical Abstract Service

EN = European norm

ISO = International Organization for Standardization

DIN = Deutsche Industrie Norm

PBT = Persistent Bioaccumulative and Toxic

vPvB = Very Persistent and very Bio-accumulative

LD = Lethal dose

LC = Lethal concentration

EC = Effect concentration

IC = Median immobilisation concentration or median inhibitory concentration

Relevant H and EUH statements (number and full text)

H225 Highly flammable liquid and vapour.

H226 Flammable liquid and vapour.

H301 Toxic if swallowed.

H302 Harmful if swallowed.

H302+H332 Harmful if swallowed or if inhaled.

H304 May be fatal if swallowed and enters airways.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H330 Fatal if inhaled.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H335 May cause respiratory irritation.

H336 May cause drowsiness or dizziness.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

H411 Toxic to aquatic life with long lasting effects.

H412 Harmful to aquatic life with long lasting effects.

EUH071 Corrosive to the respiratory tract.

Further Information

Data of items 4 to 8, as well as 10 to 12, do partly not refer to the use and the regular employing of the product (in this sense consult information on use and on product), but to liberation of major amounts in case of accidents and irregularities.

The information describes exclusively the safety requirements for the product(s) and is based on the present level of our knowledge.

The delivery specifications are contained in the corresponding product sheet.

This data does not constitute a guarantee for the characteristics of the product(s) as defined by the legal warranty regulations.

(n.a. = not applicable; n.d. = not determined)

Safety Data Sheet according to Regulation (EC) No 1907/2006

B. Braun Medical AG

Helipur H plus N

Revision date: 08.08.2018

Revision No: 1,4

Product code: 00056-0161

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)